

Notice of Allowability	Application No.	Applicant(s)	
	09/920,118	MENZEL, ROLF	
	Examiner	Art Unit	
	Patrick S. Riggins	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the amendment received 12/16/05.
2. ☒ The allowed claim(s) is/are 1-13, 15, 17-36 and 45-62.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|--|
| 1. <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____. |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____. |

EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Melissa Handler on 1/18/06.

The application has been amended as follows:

Specification:

2. Pages -i- and -ii-ii- have been deleted.
3. Page 12, lines 8-9, previously amended on 5/6/04, has been replaced with the following: --FIG. 16 *Sequence of 3A13* (SEQ ID NOs: 21 and 22) *and 5A20* (SEQ ID NOs: 19 and 20) *sequences in pGPG*. For a description of these plasmids, see Section 6.1.2.--
4. Page 12, lines 10-11, previously amended on 5/6/04, has been replaced with the following: --FIG. 17A-17B. *Sequence of complete* (A) *lichenformis* (SEQ ID NOs: 13 and 14) *(5A36) and* (B) *subtilis* (SEQ ID NOs: 15 and 16) *(3A1) subtilisins in target vector*. For details, see section 6.2.1.--
5. Page 12, line 28 "FIG. 24" has been replaced with --FIG. 24A-24B--.
6. Page 49, line 15 "seconded" has been replaced with --encoded--.
7. Page 49, line 16 "*B. subtilin*" has been replaced with --*B. subtilis*--.

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Claims:

8. In order to ensure proper antecedent basis for all terms and to maintain consistency with the format of claims 1-3, claims 14 and 16 have been canceled and new claims 60-62 have been added. The text of the claims appears below.

--60. (new) The method of claim 13, wherein the donor vector further comprises a conjugative transfer sequence.

61. (new) The method of claim 60, wherein the donor vector is transferred by conjugative transfer.

62. (new) The method of claim 15 or 61, wherein the donor vector is transformed into the bacterial cell.--

9. After this Examiner's Amendment, claims 1-13, 15, 17-36, and 45-62 are pending and found to be allowable.

REASONS FOR ALLOWANCE

10. The following is an examiner's statement of reasons for allowance:

11. In the Amendment received 12/16/05, Applicant has amended claims 1 and 13 to include the limitation that homologous recombination has occurred. This in conjunction with the limitation that at least one pair of homologous recombination modules is not identical to each other is sufficient to distinguish the instant claims from Hartley. Hartley specifically discloses the use of site-specific recombination using a recombinase such as Cre or Int. Lox sites, recognized by Cre, are indeed of sufficient length to permit homologous recombination, however for lox sites to be functional they must indeed be identical. The other embodiment described in Hartley involves Int-mediated

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recombination of att sites. While att sites are not identical, the disclosed requirement for minimal att site length required for Int-mediated recombination would not appear to be of sufficient similarity or length to permit homologous recombination.

12. Additionally, Applicant has supplied a teaching from Molecular Cell Biology (2000, newly cited) which indicates that to the skilled artisan, site-specific recombination, i.e. recombination mediated by a specific recombinase such as Cre, is considered to be a distinct process from homologous recombination (see page 488, last paragraph). It is thus considered that the claims as presently drawn are free of the prior art.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

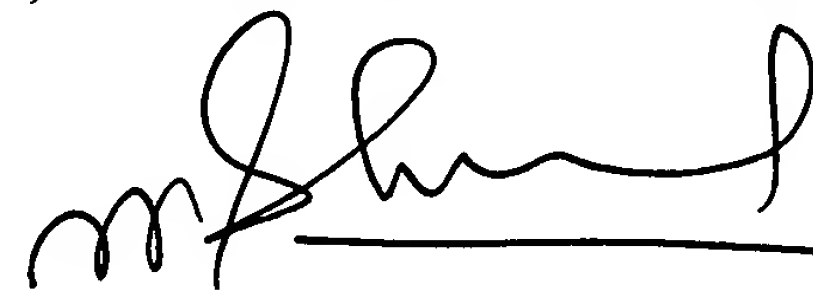
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick S. Riggins whose telephone number is (571) 272-6102. The examiner can normally be reached on M-F 7:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave T. Nguyen can be reached on (571) 272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


RAM R. SHUKLA, PH.D.
SUPERVISORY PATENT EXAMINER

Patrick Riggins, Ph.D.
Examiner
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